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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,832	09/28/1999	KEIKO YUGAWA	43888-067	1982

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EXAMINER
NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/406,832	YUGAWA ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5-20,22-37,39-54 and 56-82* is/are allowed.

6)☒ Claim(s) *21,38,55 and 83* is/are rejected.

7)☒ Claim(s) *84-86* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Arguments

1. Applicant's arguments filed August 08, 2003 have been fully considered but they are not persuasive. Applicant argues, "Aoyama does not lead one skilled in the art to the claimed subject matter" because "Aoyama does not teach the use of maleate alone" and because Aoyama teaches stabilizing glucose 6-phosphate dehydrogenase in the presence of nicotinamide adenine dinucleotide as coenzyme instead of pyrrolo-quinoline quinone. While Aoyama does not teach using maleate alone, Applicant's claims do not preclude using maleate in combination with another compound and Aoyama does disclose using maleate as part of the stabilizing compound (col. 3, ll. 30-36). Also, while Aoyama does not specifically mention glucose 6-phosphate dehydrogenase in the presence of pyrrolo-quinoline quinone as coenzyme, it is clear from his disclosure that his stabilizing compounds can be used with any glucose 6-phosphate dehydrogenase and, indeed, with a wide variety of enzymes (col. 5, ll. 46-55 and col. 6, ll. 46-52). Nicotinamide adenine dinucleotide is only an example coenzyme (col. 6, ll. 12-14).

With regard to Heisei 10-227755 ("Heisei"), Applicant refers to the previously submitted Declaration of Toshihiko Yoshioka. While Mr. Yoshioka is an author of Heisei he is also an author of the instant application. Also, other monomers are listed in paragraph [0007] of Heisei, such as acrylic acid and its salts and metaacrylic acid and its salts. So, it is not clear why just the monomer "maleic acid and its salts" is in error. Lastly, even if "maleic acid and its salts" is an accidental dislcosure in Heisei there is precedent that an accidental disclosure can be an accidental teaching. See, for example, *General Electric Company v. Watson*, Comr. Pats. 127 USPQ 326, 329.

Status of the Rejections Pending since the Office action of May 08, 2003

2. The rejection of claims 21, 38, 55, and 83 under 35 U.S.C. § 103(a) as being obvious over the English language translation of Heisei in view of Aoyama is restated below with the two motivational statements separated apart in different rejections. Also, a rejection of claims 21, 38, 55, and 83 under 35 U.S.C. § 102(a) as being anticipated by Heisei has been added.

3. The finality of the previous Office action is withdrawn. This Office action is non-final.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 21, 38, 55, and 83 are rejected under 35 U.S.C. 102(a) as being anticipated by English language translation of Heisei 10-227755. Heisei 10-227755 discloses a method for stabilizing glucose dehydrogenase for use in a glucose sensor ([Means of solution] and second sentence in paragraph [0007]) comprising an electrically insulating base plate, an electrode system including a working electrode and a counter electrode formed on the base plate (Figure 1), and a reaction layer which is formed in contact or in the vicinity of the electrode system (Figure 2), wherein the reaction layer contains glucose dehydrogenase whose coenzyme

is pyrrolo-quinoline quinone and at least one additive is added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone ([Means of solution] and paragraph [0007]). Heisei 10-227755 also discloses a list of additives (paragraph [0007]) that includes maleic acid and maleate, which are in the Markush group of additives in Applicant's claims; that is, including maleic acid in the reagent layer is within the four corners of Heisei.

For claim 83, note that although a preserved linear response as claimed is not mentioned in Heisei 10-227755, since the structure of the biosensor and the composition of the reagent layer disclosed in Heisei 10-227755 is the same as claimed by Applicant, the properties of the biosensors should be the same.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 21, 38, 55, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over English language translation of Heisei 10-227755 in view of Aoyama et al. (US 5,424,204).

Addressing claims 21, 38, and 55, Heisei 10-227755 discloses a method for stabilizing glucose dehydrogenase for use in a glucose sensor ([Means of solution] and second sentence in paragraph [0007]) comprising an electrically insulating base plate, an electrode system including

a working electrode and a counter electrode formed on the base plate (Figure 1), and a reaction layer which is formed in contact or in the vicinity of the electrode system (Figure 2), wherein the reaction layer contains glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone and at least one additive is added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone ([Means of solution] and paragraph [0007]). Heisei 10-227755 also discloses a list of additives (paragraph [0007]) that includes maleic acid, which is in the Markush group of additives in Applicant's claim.

Aoyama et al. teaches using a salt comprising maleate as a stabilizer for any glucose dehydrogenase and a wide variety of other enzymes (the abstract; col. 3, ll. 30-36; col. 5, ll. 46-55; and col. 6, ll. 46-52). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a stabilizer comprising maleate as an additive as taught by Aoyama et al. in the invention of Heisei 10-227755 because as taught by Aoyama et al. the stabilizing compound will stabilize glucose dehydrogenase in a liquid clinical assay.

Addressing claim 83, a preserved linear response as claimed is not mentioned by Heisei 10-227755 in view of the newly cited Aoyama et al.; however, since the structure of the biosensor and the composition of the reagent layer in Heisei 10-227755 as modified by Aoyama et al. are the same as claimed by Applicant, the properties of the biosensors should be the same.

8. Claims 21, 38, 55, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over English language translation of Heisei 10-227755.

Addressing claims 21, 38, and 55, Heisei 10-227755 discloses a method for stabilizing glucose dehydrogenase for use in a glucose sensor ([Means of solution] and second sentence in paragraph [0007]) comprising an electrically insulating base plate, an electrode system including a working electrode and a counter electrode formed on the base plate (Figure 1), and a reaction layer which is formed in contact or in the vicinity of the electrode system (Figure 2), wherein the reaction layer contains glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone and at least one additive is added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone ([Means of solution] and paragraph [0007]). Heisei 10-227755 also discloses a list of additives (paragraph [0007]) that includes maleic acid and maleate, which are in the Markush group of additives in Applicant's claims; that is, including maleic acid in the reagent layer is within the four corners of Heisei. It would have been obvious to one with ordinary skill in the art at the time the invention was made to choose maleic acid or a maleate from among the list of additives disclosed by Heisei 10-227755 in order to optimize the glucose sensor. Although carboxymethyl cellulose showed the best performance (paragraph [0007]), this was for limited tests, such as with an aqueous glucose solution ([Embodiment Example 1]). Heisei 10-227755 contemplates a variety of sample types, such as blood, urine, or food products (paragraph [0013]). One with ordinary skill in the art would select the additive best suited for the sample type from the disclosed list of additives.

For claim 83, note that although a preserved linear response as claimed is not mentioned in Heisei 10-227755, since the structure of the biosensor and the composition of the reagent layer disclosed in Heisei 10-227755 is the same as claimed by Applicant, the properties of the biosensors should be the same.

Allowable Subject Matter

9. Claims 5-20, 22-37, 39-54, and 56-82 are allowed.

10. Claims 84-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

a) the allowability of Claims 5-20, 22-37, 39-54, and 56-82 have been addressed in the Office action of May 08, 2003;

b) Claim 84 does not list maleic acid or maleate as a possible additive; and

c) Claims 85 and 86 depend from allowable claim 84.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola

Alex Noguerola

8/22/03